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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,340	01/19/2006	David W. Old	17609 (AP) PCT-US	2106

7590
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EXAMINER

SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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04/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,340	Applicant(s) OLD ET AL.	
	Examiner Rei-tsang Shiao, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

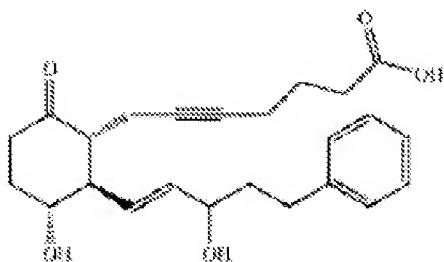
- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment of claims 1 and 21 in the amendment filed on February 28, 2008 is acknowledged. Claims 1-30 are pending in the application.

Responses to Election/Restriction

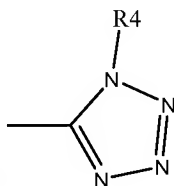
2. Applicant's election without traverse of Group I claims 1-13, in part, in the reply filed on February 28, 2008, is acknowledged. An election of a species, i.e.,



, is also acknowledged.

Claims 1-30 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 1-30, in part, drawn to compounds/compositions of formula (I), wherein the variable Z represents alkyl, cycloalkyl, aromatic radical, or heterocyclic aromatic radical selected from benzo[b]thiophen-3-yl or 3-chloro- benzo[b]thiophen-2-yl thereof;



the variable R does not represents the variable W is O, variables W, Y, R¹, R², and R³ are as defined in claim 1, and methods of use (i.e., treating ocular hypertension).

Claims 1-30, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1-30, in part, not embraced in above elected subject matter, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper.

Claim Rejections - 35 USC § 102

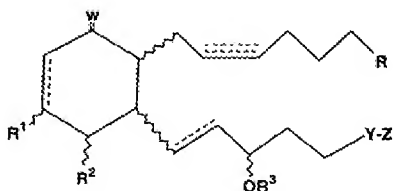
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by (1) Bernady et al. CAS: 87:22543 or see US 4,007,210; (2) Lopez-Pelegrin et al. CAS: 134:71397; (3) Ohuchida et al. CAS: 100: 209457 or (4) Floyd et al. CAS: 90:54519.

Applicants claim compounds/compositions and their methods of use (i.e., treating ocular hypertension or glaucoma) using compound of formula (I), i.e.,



, see claim 1 or 21.

Bernady et al. disclose three compounds for treating glaucoma, see RN:52419-28-0, 52419-31-5 or 52485-34-4, or see column 1 or lines 27-30 of column 43 of Bernady et al. '210.

Lopez-Pelegrin et al. disclose a compound, see RN:315220-44-1, which clearly anticipate the instant compounds of formula (I), wherein the variable W is O, the variable R is CO₂R₄, the variable R₃ is hydrogen, and the variable Z is alkyl.

Ohuchida et al. disclose a compound, see RN: 81755-81-9, which clearly anticipate the instant compounds of formula (I), wherein the variable W is O, the variable R is CO₂R₄, the variable R₃ is a lower acyl, and the variable Z is alkyl.

Floyd et al. disclose ten compounds, see RN: 61557-45-7, 61557-46-8, 61507-63-9, 61507-64-0, 61507-65-1, 61557-47-9, 61557-48-0, 61557-49-1, 61557-50-4, or 61557-51-5, which clearly anticipate the instant compounds of formula (I), wherein the variable W is O, the variable R is CO₂R₄, the variable R₃ is a hydrogen, and the variable Z is alkyl.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

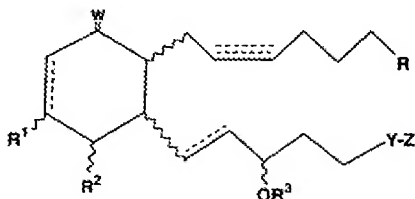
1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4.1 Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernady et al. US 4,007,210.

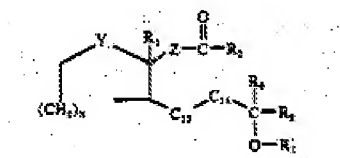
Applicants claim compounds/compositions and their methods of use (i.e., treating ocular hypertension or glaucoma) using compound of formula (I), i.e.,



, see claim 1 or 21.

Determination of the scope and content of the prior art (MPEP §2141.01)

Bernady et al. disclose compounds of the formula for treating glaucoma, i.e.,



, wherein the variable n is 1 or 2, the variable Y represents $-C=O$, the variable Z represents $-(CH_2)_m-$, the variable $C_{13}-C_{14}$ is ethylene, the variable R_1 represents hydrogen, the variable R_2 represents alkyl, see columns 1-2, and also see lines 27-30 of column 43.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and Bernady et al. is that the variable n of Bernady et al. represents 1 or 2, while the instant claims represents 2 at the same position. Bernady et al. methods of use overlap with the instant invention.

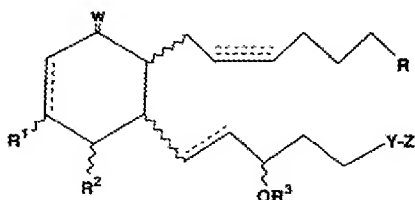
Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims 1-30 prima facie obvious **because** one would be motivated to employ the methods of use using known compounds/compositions of Bernady et al. to obtain the instant methods of use (i.e., treating ocular hypertension or glaucoma) using compounds of the formula (I), wherein the variable Z represents alkyl, cycloalkyl, aromatic radical, or heterocyclic aromatic radical selected from benzo[b]thiophen-3-yl or 3-chloro- benzo[b]thiophen-2-yl thereof. Dependent claims 2-20 and 22-30 are also rejected along with claim 1 or 21 under 35 U.S.C. 103(a).

The motivation to obtain the claimed methods of use derives from known Bernady et al. methods of use using known compounds would possess similar activities (i.e., treating ocular hypertension or glaucoma) to that which is claimed in the reference.

4.2 Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brawner et al. US 3,885,798.

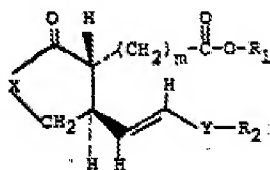
Applicants claim compounds/compositions and their methods of use (i.e., treating ocular hypertension or glaucoma) using compound of formula (I), i.e.,



, see claim 1 or 21.

Determination of the scope and content of the prior art (MPEP §2141.01)

Brawner et al. disclose compounds of the formula for treating diseases, i.e.,



, wherein the variable X represents

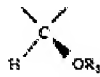


, the

variable Y represents



or



and R₃ is hydrogen, the variable R₁ or

R₂ independently represents alkyl, see columns 1-2.

Determination of the difference between the prior art and the claims (MPEP

§2141.02)

The difference between the instant claims and Brawner et al. is that the instant variable R2 represents hydrogen or hydroxyl, while Brawner et al. represents hydrogen at the same position. Brawner et al. compounds and their methods of use inherently overlap with the instant invention.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims 1-30 prima facie obvious **because** one would be motivated to employ the methods of use using known compounds/compositions of Brawner et al. to obtain the instant methods of use (i.e., treating diseases or ocular hypertension or glaucoma) using compounds of the formula (I), wherein the variable Z represents alkyl, cycloalkyl, aromatic radical, or heterocyclic aromatic radical selected from benzo[b]thiophen-3-yl or 3-chloro- benzo[b]thiophen-2-yl thereof. Dependent claims 2-20 and 22-30 are also rejected along with claim 1 or 21 under 35 U.S.C. 103(a).

The motivation to obtain the claimed methods of use derives from known Brawner et al. compounds would possess similar activities (i.e., treating diseases or ocular hypertension or glaucoma) to that which is claimed in the reference.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

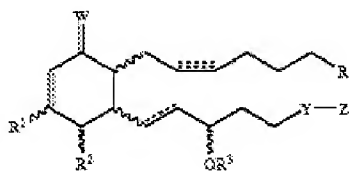
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5.1 Claims 14-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 or 3 of Old et al. US 7,015,243. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim compounds/compositions of formula (I), see claim 1.

Old et al. '243 claim compounds/compositions of formula (I), i.e.,



The difference between the instant claims and Old et al. is that the instant variable Z represents alkyl or heterocyclic aromatic radical, while Old et al. represents heterocyclic aromatic radical (i.e., benzo[b]thiophen-3-yl) at the same position. Old et al. compounds/compositions overlap the instant invention.

One having ordinary skill in the art would find the instant claims 14-30 *prima facie* obvious **because** one would be motivated to employ the compounds/compositions of Old et al. to obtain the instant compounds/composition of formula (I), wherein the variable Z represents alkyl, cycloalkyl, aromatic radical, or heterocyclic aromatic radical selected from benzo[b]thiophen-3-yl or 3-chloro- benzo[b]thiophen-2-yl thereof. Dependent claims 15-30 are also rejected along with claim 1 under the obviousness-type double patenting.

The motivation to obtain the claimed catalyst derives from known Old et al. compounds/composition would possess similar activity (i.e., treating ocular hypertension) to that which is claimed in the reference.

5.2 Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Old et al. co-

pending application No. 11/241,089. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim methods of use (i.e., treating ocular hypertension) using compounds of formula (I), see claim 1.

Old et al. '089 claim methods of use (i.e., treating ocular hypertension) using compounds of formula (I).

The difference between the instant claims and Old et al. is that the instant variable W represents O, while Old et al. represents O or halogen at the same position. Old et al. methods of use overlap the instant invention.

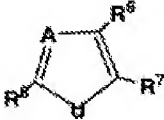
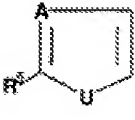
One having ordinary skill in the art would find the instant claims 1-20 *prima facie* obvious **because** one would be motivated to employ the methods of use of Old et al., wherein methods of use are treating ocular hypertension using compound of formula (I). Dependent claims 2-20 are also rejected along with claim 1 under the obviousness-type double patenting.

The motivation to obtain the claimed catalyst derives from known Old et al. methods of use would possess similar activity (i.e., treating ocular hypertension) to that which is claimed in the reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims Objection

6. Claims 1-30 are objected to as containing non-elected subject matter, i.e.,

heterocyclic or heteroaryl of variable Z, formula  or  of claim 4, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the

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Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI-TSANG SHIAO /

Rei-tsang Shiao, Ph.D.
Primary Patent Examiner
Art Unit 1626

April 15, 2008